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CARIBBEAN ENVIRONMENTAL PROTECTION DIVISION
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AUG 11 2017

CERTIFIED MAIL /RETURN RECEIPT REQUESTED

Article Number: 7011 2000 0001 4353 3365

Mr. Alvin E. Crespo, Director
Environmental Health and Safety
Bristol-Myers Squibb Manufacturing Company
Humacao Operations
P.O. Box 609
Humacao, Puerto Rico, 00792-1255

Re: Technical Review of the May 15, 2017 Response to EPA comments on the September 2016 Release Assessment Phase I Technical Memorandum for the Bristol-Myers Squibb Manufacturing Company, Humacao, Puerto Rico
EPA ID Number: PRD 090021056

Dear Mr. Crespo:

The United States Environmental Protection Agency-Region 2 (EPA) has reviewed the May 15, 2017 Response to EPA comments provided in the revised Final Release Assessment Phase 1 Technical Memorandum and its attached response in Appendix A, submitted by Bristol-Myers Squibb Manufacturing Company (BMSMC) for its facility in Humacao, Puerto Rico. After our review, EPA found that BMSMC still needs to address minor deficiencies in the Technical Memorandum. Our comments on the Response are detailed in the enclosure to this letter.

Please provide your response to the enclosed comments within 30 days of receipt of this letter. If you have any questions regarding this correspondence, please contact Socorro Martinez of my staff at (787) 977-5886 or via email at martinez.socorro@epa.gov.

Sincerely,

Carmen R. Guerrero-Pérez
Director
Caribbean Environmental Protection Division

cc: Manuel O. Claudio Rodríguez, Manager,
Land Pollution Control Program, PREQB

Enclosure

The review of this letter indicates that BSMC has agreed to sample and analyze Phase 2A monitoring wells for the full target compound list (TCL) volatile organic compounds (VOCs), full TCL semi-volatile organic compounds (SVOCs), extractable petroleum hydrocarbons (EPA), volatile petroleum hydrocarbons (VPH), low molecular weight alcohol (LMA), organochlorine pesticides, plus tetrahydrofuran, p-isopropyl toluene, 1,2,4-trimethylbenzene, benzyl chloride, tert-amyl alcohol, 1-methylnaphthalene, naphthalene, 1,4-dioxane for four quarters (June 2017, September 2017, and December 2017, and March 2018 quarterly sampling events). In addition to sampling the Release Assessment Phase 2A monitoring wells, BSMC should be collecting and analyzing the southern and eastern perimeter (or boundary) Phase 1 Release Assessment monitoring wells for the same parameters. Data from these Phase 1 Release Assessment monitoring wells will be critical in evaluating the merits of BSMC's proposal to reduce the target analyte list and to revert to the sampling approach outlined in the November 2016 Technical Memorandum Proposed Sampling Program Offsite Groundwater – South of the Facility.

TECHNICAL REVIEW

May 15, 2017

RESPONSE TO COMMENTS ON SEPTEMBER 2016 RELEASE ASSESSMENT PHASE 1 TECHNICAL MEMORANDUM

BRISTOL-MYERS SQUIBB MANUFACTURING COMPANY

HUMACAO, PUERTO RICO

I. INTRODUCTION

EPA provided comments on the 2016 Release Assessment Phase 1 Technical Memorandum on October 2016. On May 15, 2017, BMSMC provided a Final Release Assessment Phase 1 Technical Memorandum and attached the response to the EPA comments (RTCs) in Appendix A. The majority of comments have been adequately addressed, but specific concerns regarding the RTCs are provided below. In addition, the review of this letter indicates that BMSMC has agreed to sample and analyze Phase 2A monitoring wells for the full target compound list (TCL) volatile organic compounds (VOCs), full TCL semi-volatile organic compounds (SVOCs), extractable petroleum hydrocarbons (EPA), volatile petroleum hydrocarbons (VPH), low molecular weight alcohol (LMA), organochlorine pesticides, plus tetrahydrofuran, p-isopropyl toluene, 1,2,4-trimethylbenzene, benzyl chloride, tert-amyl alcohol, 1-methylnaphthalene, naphthalene, 1,4-dioxane for four quarters (June 2017, September 2017, and December 2017, and March 2018 quarterly sampling events). In addition to sampling the Release Assessment Phase 2A monitoring wells, BMSMC should be collecting and analyzing the southern and eastern perimeter (or boundary) Phase 1 Release Assessment monitoring wells for the same parameters. Data from these Phase 1 Release Assessment monitoring wells will be critical in evaluating the merits of BMSMC's proposal to reduce the target analyte list and to revert to the sampling approach outlined in the November 2016 Technical Memorandum Proposed Sampling Program Offsite Groundwater – South of the Facility.

II. GENERAL COMMENTS

1. **Original EPA Comment:** Although the current use of the BMSMC facility is industrial/commercial and a future deed restriction may ensure that remains the case, soil and groundwater data should also be compared to the residential RSLs due to the potential for off-site migration of groundwater contamination. On-site groundwater and soil should also be characterized to the residential RSLs so that the potential for newly identified COCs to migrate off-site can be established and fully characterized.

BMSMC Response: The September 2016 *Release Assessment Phase 1 Technical Memorandum* has been revised to incorporate a comparison of the sampling data to

residential soil and groundwater RSLs.¹ Specifically, residential direct contact screening levels have been added to tables that present soil analytical results, including **Tables 11-14.**² Residential groundwater concentrations for vapor intrusion screening levels have been added to tables that present groundwater analytical results, including **Tables 15-17.** Section 4.3, 4.4, 4.6, and 5.0 have also been revised to incorporate a discussion of residential soil and groundwater RSLs. BMSMC would like to emphasize that its intention to incorporate a future deed restriction at the facility limited development to commercial/industrial use.

EPA Comment: The response to this comment is acceptable and the response was adequately incorporated into Tables 11-17, Section 4.3, 4.4, 4.6, and 5.0.

2. **Original EPA Comment:** The sampling design in the Release Assessment Phase 1 SAP does not include surface soil samples (i.e., 0-2 feet below ground surface soil interval). Not obtaining surface soil data for the newly identified potential constituents of concern (COPCs) may represent a data gap for the human health risk assessment that will be complete as part of the Corrective Measures Study. Recommend that BMSMC review the existing data and determine if additional sampling is needed in a subsequent phase of the release assessment in order to have sufficient data for a human health risk assessment.

BMSMC Response: Soil analytical data collected from the 0 to 2 feet below ground surface interval were presented and discussed in the July 2011 *Corrective Measure Study Report*. In February 2015, BMSMC received comments from the USEPA on the July 11 *Corrective Measure Study Report* which indicates USEPA's current recommendations that surface soil sample should be collected from the 0 to 2 inch surface soil layer to evaluate surface soil exposure.

In support of BMBMC's July 2015 Response to the USEPA Comments on the July 2011 Corrective Measures Study Report, BMSMC submitted an Onsite Surface Soil Sampling and Analysis Plan to the USEPA in January 2017 to evaluate the 0 to 2 inch surface soil exposure pathway. Surface soil sample were collected in January 2017. The results of the onsite surface soil sampling will be presented and discussed in a future Release Assessment Onsite Surface Soil Technical Memorandum (target submittal May 2017).³

EPA Comment: The response to this comment is acceptable.

3. **Original EPA Comment:** As previously commented on the Release Assessment Phase 2A SAP, BMSMC has already reduced the target analyte list being reported in the Phase 2A Release Assessment to six COPCs (i.e., benzene, methyl-tert-butyl ether, tert-amyl alcohol, 1,4-dioxane, naphthalene, and C11-C22 aromatics) from the 43 COPCs that were identified in the February 2016 Release Assessment Report (RAR). Based on a review of this memorandum, EPA still strongly advises BMSMC to not prematurely reduce the COPC list and report the full target analyte list for SW-846 Method 8260C, SW-846 Method 8270D, SW-846 Method 8270D SIM, SW-846 Method 8081B, MADeP-VPH-01-1.1, and MADEP-EPA-04 during Phase 2A of the release assessment.

¹ Both USEPA and PREQB screening levels are addressed in the revised technical memorandum.

² PREQB industrial soil screening levels have also been added to **Tables 11-14.**

³ The results of the surface soil sampling program were also presented in the April 2017 *Quarterly Progress Report No. 66 1st Quarter 2017* which was previously submitted to USEPA.

BMSMC Response: As per USEPA's request., starting with the June 2017 sampling event, groundwater samples collected from the Release Assessment Phase 2A monitoring wells will be sampled for the full target compound list (TCL) VOCs Plus Tetrahydrofuran, p-Isopropyl Toluene, Tert-Amyl Alcohol, Benzyl Chloride, and 1,24-Trimethylbenzene according to SW-846 Method 8260C, full TCL SVOCs plus 1-Methylphthalene, according to SW-846 Method 8270D, Naphthalene and 1,4-Dioxane according to SW-846 Method 8270D SIM, Organochlorine Pesticides according to SW-846 Method 8081B, VPH according to MADEP VPH-Revision 1.1, and EPA according to MADEP EPH Revision 1.1. Additional, BMSMC will test for low molecular weight alcohols (LMAs) according to SW-846 Method 8015C by DAI.

EPA Comment: The response to this comment is partially acceptable. In addition, to sampling the Release Assessment Phase 2A monitoring wells, BMSMC should be collecting and analyzing for the same parameters in the southern and eastern perimeter (or boundary) Phase 1 Release Assessment monitoring wells. Specifically, BMSMC should be sampling monitoring wells MW-20D, MW-20S, S-43S, S-43D, S-42S, S-42D, S-35-D, S-41S, S-41D, S-40S, and S-40D for the additional parameters discussed above. Data from these Phase 1 Release Assessment monitoring wells will be critical to evaluating the merits of BMSMC's proposal to reduce the target analyte list and to revert to the approach outlined in the November 2016 Technical Memorandum Proposed Sampling Program Offsite Groundwater – South of the Facility.

III.SPECIFIC COMMENTS

Section 3.4., Shallow and Deep In-Situ Groundwater, Pages 10-12 and Appendix A Release Assessment Phase 1 Soil Boring Logs and Monitoring Well Construction Diagrams

1. **Original EPA Comment:** The text indicates that shallow in-situ groundwater samples were collected at the top of the first saturated zone and deep in-situ groundwater samples were collected the base of the first saturated zone. Suggest clarifying that the in-situ groundwater samples were only collected from the uppermost saturated zone and the borings were not extended below the clay layer. In addition, BMSMC should evaluate the potential for vertical migration of groundwater contamination on/off site and this analysis should be presented in the full Release Assessment Sampling and Analysis Report.

BMSMC Response: The September 2016 *Release Assessment Phase 1 Technical Memorandum* (Section 3.4) has been revised to clarify that in-situ groundwater samples were only collected from the uppermost saturated zone.

An evaluation of the potential migration of groundwater contamination below the uppermost saturated zone will be conducted as part of Release Assessment Phase 3 activities.

EPA Comment: The response to this comment is acceptable and the response was adequately incorporated into Section 3.4.

2. **Original EPA Comment:** The text indicates that groundwater screen for the shallow in-situ groundwater samples were generally extended from one foot above the top of the saturated zone to one to three feet below the top of the saturated zone. Based a review of the boring

logs in Appendix A, the text seems to be inaccurate and the screen intervals were not consistently set in at the top of the unsaturated zone and beginning of the saturated zone. Revise the text accordingly and include the depth that groundwater was first groundwater was encountered on Table 7.

BMSMC Response: The specific placement of the in-situ well screens at the top of the saturated zone was determined based on lithology, moisture content, and the ability of screened formation to yield sufficient water to collect a groundwater sample. Additional discussion of the placement of the well screens across the top of the uppermost saturated zone has been included in Section 3.4 of the revised September 2016 *Release Assessment Phase 1 Technical Memorandum*. In addition, **Table 7** has been revised to include the depth at which groundwater was encountered in each direct push soil boring.

EPA Comment: The response to this comment is acceptable and the response was adequately incorporated into Section 3.4 and Table 7.

3. **Original EPA Comment:** For in-situ deep groundwater samples, the text indicates that groundwater screen was generally extended from one to three feet above the confining to one foot below the confining layer. Based a review of the boring logs in Appendix A, indicates that text appears to be inaccurate and the screen intervals were not consistently set above/within the clay layer. For example, the boring log for R-4 states that the groundwater screen was set at 13 feet below ground surface and the clay layer was first encountered at 8 feet below ground surface (bgs). Update the text to accurately reflect where the groundwater screen was set for the in-situ deep groundwater samples during the Phase 1 field activities.

BMSMC Response: The specific placement of the in-situ well screens at the base of the saturated zone was determined based on lithology, moisture content, and the ability of the screened formation to yield sufficient water to collect a groundwater sample. Additional discussion of the placement of the well screens across the top and bottom of the uppermost saturated zone has been included in Section 3.4 of the revised September 2016 *Release Assessment Phase 1 Technical Memorandum*. The lithology encountered during the completion of soil boring RA-4 was atypical in that most of the boring consisted of clay with some silt and trace sand. A thin one-foot thick sand lens was encountered from 6 to 7 feet bgs from which the shallow in-situ groundwater sample was collected. The deep in-situ groundwater sample was collected from within the clay where thin water-bearing silt zones were encountered.

EPA Comment: The response to this comment is acceptable and the response was adequately incorporated into Section 3.4.

4. **Original EPA Comment:** Footnote #10 states five groundwater samples were not analyzed for organochlorine pesticides. Please indicate the effect this has on completeness of the organochlorine pesticide data set and whether additional sampling in warranted to fill the data gaps. In addition, this footnote indicates that RA19-GWS was not analyzed due to laboratory error. Please provide additional details explaining why the laboratory did not analyze the sample.

BMSMC Response: Organochlorine Pesticides are routinely analyzed in all Building 5 Area wells, upgradient wells installed during the Phase 1 Release Assessment, as well as

certain monitoring wells installed during the Phase 1 Release Assessment. Specific monitoring wells routinely sampled for Organochlorine Pesticides include A-1R4, A-2R2, D-1R, E-1R, G-1R3, MS-11, S-28, S-29R, S-30, S-31R2, S-32, S-33, S-34, S-35D, S-35S, S-36, S-37, S-38, S-39D, S-39S, UP-1, UP-2, MW-20D, MW-20S, MW-21D, MW-21S, MW-22D, MW-22S, RA-10D, RA-10S, S-40D, S-40S, S-41D, S-41S, S-42D, S-42S, S-43D, and S-43S. A review of groundwater analytical data collected from March 2016 through December 2016 indicates Organochlorine Pesticides have only been occasionally detected in two building 5 monitoring wells (E-1R and UP-1). BMSMC believes the current groundwater sampling program is adequate to evaluate the presence/absence of Organochlorine Pesticides impact to groundwater. Additional discussion on Organochlorine Pesticides in groundwater has been included in Section 4.6 of the revised September 2016 *Release Assessment Phase 1 Technical Memorandum*. RA19-GWS was not analyzed for Organochlorine Pesticides since the laboratory inadvertently disposed of the sample volume before analysis. This detail has been added to Footnote No. 10.

EPA Comment: The response to this comment is acceptable; however, Section 4.6 does not appear to be updated to reflect this response.

Section 4.3.2, Total Petroleum Hydrocarbons (TPH) and Poly Aromatic Hydrocarbons (PAHs),
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5. **Original EPA Comment:** Footnote #12 states that TPH concentrations to be adjusted to filter out target compounds (e.g., ethylbenzene) for which USEPA has developed parameter – specific screening levels in the human health risk assessment. It is not appropriate to propose adjustments for the human health risk assessment in Release Assessment Phase 1 Technical Memorandum and it should be deleted from this memorandum.

BMSMC Response: For the September 2016 *Release Assessment Phase 1 Technical Memorandum*, unadjusted TPH concentrations were compared to the USEPA RSLs, although there is not necessarily a one to one correlation between the TPH fraction and the USEPA screening levels. This is appropriate for a screening level evaluation of TPH to determine the overall presence of petroleum hydrocarbons in soil and groundwater. At USEPA's request, Footnote 12 has been removed. AMSMC also proposes that prior to revisiting the human health risk assessment, a meeting be held with USEPA to discuss the use of TPH data in the human health risk assessment.

EPA Comment: The response to this comment is acceptable and Section 4.3.2 was revised accordingly.